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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,201	11/08/2000	William M. Mitchell	50150/007002	4075

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/25/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/709,201

Applicant(s)

MITCHELL ET AL.

Examiner

Ja-Na A Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48 and 68-75 is/are pending in the application.
- 4a) Of the above claim(s) 74 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48 and 68-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restriction

1. Claims 1-47, 49-67 have been cancelled. Claims 74-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 10. Claims 48 and 68-73 drawn only to SEQ ID NO:97 are ~~pending~~ ^{*under consideration*} in this Office Action.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 48 of this application. This application claims priority to application number 08/911,593, however this application was abandoned as an incomplete file. Due to this incompleteness, priority cannot be granted.

Claim Objections

3. Claims 70 and 73 are objected to because of the following informalities: The claims refer to non-elected SEQ ID Numbers. Appropriate correction is required.

Drawings

4. The drawings are objected to because of the reasons set forth in the attached PTOL-948. However, the corrections will not be held in abeyance and applicant must submit proposed drawing corrections in response to the requirement in the Office action.

Specification

5. The use of the trademark SUCCIMER and other chemicals and diagnostic tools associated with immunodiagnostic work have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 48 and 68-73 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MEP. § 2172.01. The omitted steps are: There are no contact steps, detection steps or correlation step in the claims. None of the claims recite actual method steps that would allow one to practice the invention. For instance, claim 48 simply recites performing on the sample an antigen capture assay without positively reciting any steps.

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8. Claims 48 and 68-73 are unclear because using antibodies to bind the peptide, however it is unclear where the antibodies came from. There is no recitation by the claim as to making the antibodies, thus the antibodies must be obtained before they are used in the assay. Also, there is no label associated with the antibody used in the claims, therefore it is unclear how one can detect the antibody or detect the presence of Chlamydia without some type of detectable label.

Clarification is requested.

9. Claim 68 is unclear, the claim says contacting said sample with an antibody. It is unclear if the sample already comprises the antibody or if the sample is contacted with the antibody.

Clarification is requested.

10. Claims 68 and 71 recite the limitation "said sample" in the claims. There is insufficient antecedent basis for this limitation in the claim. Moreover, no sample was previously mentioned within the claims, therefore clarification is required.

11. Claim 71 recites immobilizing the sample onto a substrate. It is unclear if all of the sample is immobilized and then the immobilized sample is contacted with the antibody ^{or} if applicants intend something else. It is unclear how one will immobilize the entire sample.

Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 48 and 68-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroiwa et al., (EP 699,688) in view of Melgosa et al.

Kuroiwa et al., teach monoclonal antibodies which react with *Chlamydia pneumonia* and methods of detection and measurements of *Chlamydia*, along with reagents for the method (page 2 lines 1-5). Antigens of *Chlamydia* are known and include Major Outer Membrane Proteins (MOMP) (page 2 lines 24-34). The monoclonal antibody of this invention reacts specifically with *Chlamydia pneumonia* derived MOMP; it is reactive with an elementary body of *Chlamydia pneumonia*; and the antibody can be labeled (page 3 lines 10-21). A method of detection and/or measuring *Chlamydia* ^{which} uses the monoclonal antibody is also taught (page 3 lines 51-54).

Reactivity to MOMP of *Chlamydia* can be evaluated by detecting ~~the~~ the presence of an antibody which specifically reacts with a band of MOMP by a Western blot method using Elementary Bodies (BE) of *Chlamydia* which is treated with an appropriate solution (page 5 lines 56-58). Monoclonal antibodies can be labeled using various kinds of dyes, colloids and enzymes (page 6 lines 37-38). Indirect or direct labeling of the antibody can detect *Chlamydia* (page 6 lines 50-51). If the labeling agent is an enzyme, a substrate is added and luminescent or color development ~~occurs~~ occurs such that the enzyme is detected and measured (page 6 lines 55-58).

The antibodies can be used in methods for detecting a desired protein, using immunoreactions

such as radioimmunoassay, enzyme-immunoassays and the like (page 7 lines 25-28). However, Kuroiwa does not teach the binding of a peptide consisting of SEQ ID NO:97.

Melgosa et al., teach sequence analysis of the Major Outer Membrane Protein (MOMP) gene of *Chlamydia pneumoniae*. The MOMP genes of several strains of *Chlamydia* have been found to be highly conserved (page 2195). An Immunoblot analysis of anti-*C.pneumoniae* sera or human sera recognizes the MOMP peptide (page 2195). Melgosa et al., teach the sequence of the claimed peptide. All the monoclonal antibodies that have been prepared were able to recognize the MOMP are genus specific (page 2198).

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the methods taught by Kuroiwa et al., to detect *Chlamydia* by using antibodies which bind to highly conserved regions of *Chlamydia* species. One would have a reasonable expectation of success because no more than routine skill would have been required to exchange the antibody used to detect *Chlamydia* when antibodies to detect *Chlamydia* are well known in the art to detect such. Moreover, the antibodies are available and capable of recognizing *Chlamydia* in a variety of immunoassays.

Prior Art

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Carter et al., teach nucleotide sequence of the MOMP. Gaydos et al., teach the similarity of *Chlamydia pneumoniae* strains in the variable regions of the MOMP gene. Pronovost (US Patent 5,047,326) teaches immunological methods for the detection of *Chlamydia*. Watanabe et al., (US Patent 5,318,892) teach methods for assaying *Chlamydia* with an antibody to a MOMP.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines *QJ*
March 17, 2003

LFS
LYNETTE R. F. SMITH
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